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09/922,555	08/03/2001	Michael J. O'Neill	2507/101	9456

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EXAMINER

WOO, JULIAN W

ART UNIT

PAPER NUMBER

3731

DATE MAILED: 02/28/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/922,555

Applicant(s)

O'NEILL, MICHAEL J.

Examiner

Julian W. Woo

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on 4/2/02.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-59 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-15 and 54-59 is/are allowed.
- 6) ☒ Claim(s) 16-31, 33, 34, 36-48 and 50-53 is/are rejected.
- 7) ☒ Claim(s) 32, 35, 49 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

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## **DETAILED ACTION**

### ***Reissue Applications***

1. The reissue oath/declaration filed with this application is defective because it fails to identify at least one specific error, limitation, or addition, which is relied upon to support the reissue application. See 37 CFR 1.175(a)(1) and MPEP § 1414.

2. Claims 1-59 are rejected as being based upon a defective reissue declaration under 35 U.S.C. 251 as set forth above. See 37 CFR 1.175.

The nature of the defect(s) in the declaration is set forth in the discussion above in this Office action.

3. This application is objected to under 37 CFR 1.172(a) as the assignee has not established its ownership interest in the patent for which reissue is being requested. An assignee must establish its ownership interest in order to support the consent to a reissue application required by 37 CFR 1.172(a). The assignee's ownership interest is established by:

(a) filing in the reissue application evidence of a chain of title from the original owner to the assignee, or

(b) specifying in the record of the reissue application where such evidence is recorded in the Office (e.g., reel and frame number, etc.).

The submission with respect to (a) and (b) to establish ownership must be signed by a party authorized to act on behalf of the assignee. See MPEP § 1410.01.

An appropriate paper satisfying the requirements of 37 CFR 3.73 must be submitted in reply to this Office action.

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4. This application is objected to under 37 CFR 1.172(a) as lacking the written consent of all assignees owning an undivided interest in the patent. The consent of the assignee must be in compliance with 37 CFR 1.172. See MPEP § 1410.01. The "Assent by Assignee for Filing of Reissue Application," filed on November 13, 2001, cites an attachment of a statement under 37 C.F.R. section 3.73(b), but the statement is missing from the file.

A proper assent of the assignee in compliance with 37 CFR 1.172 and 3.73 is required in reply to this Office action.

***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 16-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. With respect to base, independent claims 16 and 18 and dependent claims 20, 21, and 24, the phrase, "set of at least one dilation channels," is grammatically incorrect, and it is not certain how a set of channels can comprise only one channel.

***Claim Rejections - 35 USC § 102***

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 26-28 and 30 are rejected under 35 U.S.C. 102(e) as being anticipated by McPherson et al. (5,687,739). McPherson et al. disclose in figure 1 and in col. 3, lines 12-59, a harvesting apparatus usable in bone, where the apparatus includes a polycarbonate collection shaft (14) and a stainless steel cutting tip (34) with openings (at each end of the tip) that can be permanently attached, bonded, or mechanically fastened to the shaft via threads (16) on the shaft.

9. Claims 31 and 33 are rejected under 35 U.S.C. 102(b) as being anticipated by Chiou (5,492,130). Chiou discloses, in figures 2-4, a harvesting apparatus usable in bone, where the apparatus comprises a cutter device with a collection shaft (21) and a depth gage (at 7) at the proximal end of the shaft.

10. Claims 34, 36, 37, and 41 are rejected under 35 U.S.C. 102(e) as being anticipated by Russin (5,807,276). Russin discloses, in figures 1-3 and 12 and in col. 7, lines 35-67, a method of harvesting bone that includes docking a channel or dilation channel (82) to a bone harvest site after percutaneous insertion at an incision, inserting a bone harvesting device (a "biopsy needle" or 18) into the channel, and moving the channel in an arcing motion (i.e., "rotating the K-wire tube (84) about the K-wire (12) to radially position the metal target tube (86) in a desired radial position about the K-wire").

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***Claim Rejections - 35 USC § 103***

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

12. Claims 36 and 38-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cibley (4,461,305). Cibley discloses, in figure 1 and in col. 3, lines 20-35, for instance, a method of harvesting tissue substantially as claimed, where the method includes docking a channel (20) to a harvest site and inserting a harvesting device (10) into the channel, where the channel has a means for docking or a pair of members (22) protruding from its distal end and an arcuate, sharp edge at its distal end. However, Cibley does not disclose harvesting of bone. Nevertheless, it would have been obvious to one having ordinary skill in the art at the time the invention was made, to apply Cibley's method to the harvesting of bone. Bone is simply another bioptic tissue that can be conveniently and automatically harvested with Cibley's method.

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13. Claims 26, 29, 42-48 and 50-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chiou (5,492,130). Chiou discloses, in col. 4, lines 8-11 and in col. 7, lines 22-39, for instance, a method of harvesting tissue substantially as claimed, where the method includes inserting, in a percutaneous incision and a guided delivery system (1), a hollow cylindrical coring device (21) with a permanently attached, stainless steel cutting tip (22) having openings at its ends and downwardly directing and rotating the coring device in clockwise and counterclockwise directions (i.e., twisting or "[moving the] device slightly...to allow jagged cutting edge (35) to sever any portion of the [tissue] sample...." The cutting tip is bonded or mechanically fastened (at 24) to the coring device. However, Chiou does not disclose a method of harvesting bone, nor does Chiou disclose ultrasonically welding the cutting tip to the coring device. Nevertheless, it would have been obvious to one of ordinary skill in the art at the time the invention was made, to apply Chiou's method to the harvesting of bone. Bone is simply another bioptic tissue that can be conveniently harvested with Chiou's method. Also, it would have been a matter of design choice to apply ultrasonic welding in the fashioning of the tubular coring device (at intermediate section 24). Such a mode of manufacture would produce a void-free, integrated, and strong structure necessary for Chiou's coring device.

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***Allowable Subject Matter***

14. The original patent, or a statement as to loss or inaccessibility of the original patent, must be received before this reissue application can be allowed. See 37 CFR 1.178.

15. Claims 1-15 and 54-59 would be allowable upon receipt of an appropriate supplemental oath/declaration under 37 CFR 1.175(b)(1) that will overcome the rejection under 35 U.S.C. 251.

16. Claims 32, 35, and 49 would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims and upon receipt of an appropriate supplemental oath/declaration under 37 CFR 1.175(b)(1) that will overcome the rejection under 35 U.S.C. 251.

17. Claims 16 and 18 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, and upon receipt of an appropriate supplemental oath/declaration under 37 CFR 1.175(b)(1) that will overcome the rejection under 35 U.S.C. 251.

18. Claims 17 and 19-25 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, and include all of the limitations of the base claim and any intervening claims and upon receipt of an appropriate supplemental oath/declaration under 37 CFR 1.175(b)(1) that will overcome the rejection under 35 U.S.C. 251.

19. The following is a statement of reasons for the indication of allowable subject matter: None of the prior art of record, alone or in combination, discloses an



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apparatus and a method of harvesting bone, where the method includes, inter alia, guiding a cylindrical obturator on a guide wire inserted in bone, placing a cylindrical tissue dilator concentrically over the obturator, removing the guide wire and obturator from the bone, placing an impactor cap over the dilator, and inserting a hollow cutting cylinder into the dilator; and where the apparatus includes, inter alia, a guide wire; a generally cylindrical, and hollow obturator; a generally cylindrical, and hollow dilator positionable over the obturator, and a generally cylindrical, hollow, and forked cannula positionable over dilator. The prior art of record also does not disclose a coring device with a hollow cylindrical shaft and a cutting tip attached to the shaft, where the tip has two protruding blades joined at one end. None of the prior art of record discloses a method of harvesting bone, where method includes, inter alia, inserting a guidance member at a bone harvest site, sequentially positioning a plurality of or a set of dilation channels is over the guidance member, and inserting a cutter device through a member of the set of dilation channels. The prior art of record also does not disclose a bone harvesting apparatus including a cutter device with a depth gage at the proximal end of a collection shaft and calibration marks at the distal end for indicating harvested bone volume. The prior art of record does not disclose a method of harvesting bone, where a hollow cylindrical coring device is inserted through a guided delivery system and a downward force is directed against a bone harvest site, where the device includes a downward-facing cutting edge extending circumferentially around less than a full circle.

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***Conclusion***

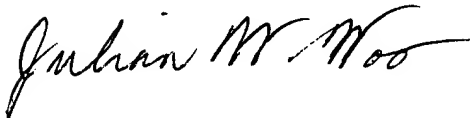
20. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Joishy (5,012,818) and Bobic (5,919,196) teach coring devices with calibration marks. Allen (5,341,816) teaches a coring device with a removable cutting tip.

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21. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julian W. Woo whose telephone number is (703) 308-0421. The examiner can normally be reached Mon.-Fri., 7:00 AM to 3:00 PM Eastern Time, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael J. Milano can be reached at (703) 308-2496.

General inquiries relating to the status of this application should be directed to the Group receptionist at (703)308-0858. The FAX number is (703)872-9302.

A handwritten signature in cursive script that reads "Julian W. Woo". The signature is written in dark ink and is positioned above the printed name and title.

Julian W. Woo  
Patent Examiner

February 24, 2003